

AMENDMENTS TO THE DRAWINGS

Please replace with sheet 4 of the formal drawings filed April 23, 2004 with the enclosed replacement sheet. The only change is in the label of the x-axis. "Depth, cm" has been changed to "Depth, mm"

REMARKS

Status of the Claims

Claims 1-74 have been examined in the present application. Claims 1, 7, 11-14, 20-29, 32-34, 37-49, 52 and 54 are currently amended. Claims 16-19, 30-31, 36 and 62-68 are cancelled. Claims 69-74 are new. In light of these amendments and the remarks herein, Applicants request reconsideration of the claims.

Objections to the Specification

The Examiner has objected to the sentence at page 22, lines 25-29 of the specification. Applicants believe that this was a typographical error. However, to avoid any confusion and to avoid potentially introducing new matter into the specification, Applicants have amended the paragraph to eliminate the sentence entirely, which is not essential to the specification or the claims.

The Examiner has objected to the discussion regarding hypothermia at page 25, lines 11 and 20. However, the Applicants believe that the information is correct. Although it is believed that hypothermia generally decreases the efficacy of biostimulation, there are some cases where hypothermia increases the efficacy of biostimulation.

The Examiner has objected to the discussion regarding Figures 6 and 7 at page 26, line 24. However, the Applicants believe that the information disclosed is correct. In the broader ranges, hyperthermia can be achieved at the deeper depths disclosed. Figure 7, on the other hand, depicts the results of specific cases within the broader ranges.

The Examiner has objected to the discussion regarding Figure 7 at page 27, line 16. The Applicants submit that tabular data is provided in Table 3. However, to avoid any confusion, Applicants have amended the paragraph to eliminate the reference to tabular data, which is not essential to the specification or the claims.

Objections to the Drawings

The Examiner objected to FIG. 2, because it does not show a cooling means as described on page 24. However, the applicants submit that the paragraph contains a typographical error.

Rather than refer to FIG. 2, the passage should have referred to FIG. 4, which does show a cooler 412. Therefore, the Applicants have amended the specification accordingly. The applicants submit that no new matter has been added at this time, because the detailed description of cooling has not been changed and was present in the specification at the time of filing.

The Examiner objected to FIGS. 6 and 7 because one has units of depth in millimeters while the other has units of depth in centimeters. Accordingly, Applicants have amended FIG. 6 to change the units from centimeters to millimeters. Applicants submit that this change does not add new matter to the specification, because the specification, the corresponding units in FIG. 7, and the references to the depths of skin and subcutaneous fat in FIG. 6 itself make clear that the units of centimeters in FIG. 6 was an error. For example, the discussion of depth in the specification is in units of millimeters and there is no discussion of depth in units of centimeters.

Amendments to the Claims

To expedite prosecution of this application, Applicants present the following amendments without prejudice. Such amendments, however, provide no evidence regarding the propriety of any rejections regarding the filed claims in light of the cited art. Applicants maintain the right to pursue any of the filed claims in one or more continuing applications.

Independent claim 1 is amended to include controlling a flux of said radiation to achieve a desired temperature profile in the target region; wherein said target region is irradiated for a time duration selected to achieve the desired biostimulation of the target region. Claims 7, 11-14, 20-25, 32-34 and 37-38 are amended to include language consistent with amended claim 1, from which each depends, and, in some cases, to change the dependency of the claims. Claims 26-29 are amended to claim methods in which the radiation for biostimulation and the radiation for controlling the temperature profile are produced from the same source and also claim methods in which each is produced from different sources.

Independent claim 39 is amended to recite irradiating the volume of tissue with a first radiation from a first radiation source, the first radiation having one or more wavelengths to biostimulate the volume of tissue; and irradiating the volume of tissue with a second radiation from a second radiation source; and modulating a flux of said second radiation to control the

temperature within at least a first portion of the volume of tissue. Correspondingly, claims 40-47 and 49 are amended to provide language consistent with amended claim 39, from which each depends. Claims 41 and 49 were amended to change the dependency of each, and claim 49 was rewritten from a device to a method claim.

Independent claim 48 is amended to recite a second source for generating electromagnetic radiation configured to modulate a flux of radiation from said second source for controlling a temperature profile within at least a first portion of said target region. The requirement of a cooler was eliminated, and, instead, a cooling element was included in amended dependent claim 52. Claim 54 was amended to include language consistent with amended claim 48, from which it depends. Claims 69-74 are newly added claims that are dependent from amended claim 48.

Support for each of the amendments can be found throughout the specification. In particular, support for devices and methods in which the flux of radiation controls the temperature in tissue is found in the specification at paragraphs 79-84 as well as in many other parts of the specification. Support for a device having a single radiation sources capable of biostimulating tissue and heating tissue is also disclosed, among other places, in paragraphs 79-84. Similarly, support for a device having two different sets of radiation sources capable of biostimulating tissue and heating tissue respectively is disclosed, among other places, in paragraph 65.

Since all the amendments are supported within the filed application, no new matter is introduced.

Claim Objections

The Examiner objected to claims 16, 23 and 40 as being of improper dependent form. Claim 16 is cancelled. The applicants believe that the amendments to claims 23 and 40 adequately address the Examiner's objection.

Claim Rejections – 35 U.S.C. § 112

Claims 23, 40, 43 and 49 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the

applicant regards as the invention. Applicants have amended claims 23 and 40 to remove the reference to the “efficacy of biostimulation.” Applicants have provided antecedent basis for “said volume” in claim 43. Applicants have amended claim 49 from a device to a method claim. Applicants believe these amendments adequately address the examiner’s rejections.

Claim Rejections – 35 U.S.C. § 102

Claims 1-3, 5-8, 16-17, 20-26, 32-33, 35-45, 47-51, 54, 56 and 62-67 are rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent 6,273,884 to Altshuler et al. (herein “Altshuler”) Applicants submit that the amendments to independent claims 1, 39 and 48 overcome the Examiner’s rejections. Although the Applicants disagree with the Examiner’s application of Altshuler to the rejected claims, the amended claims recite an aspect of the disclosed invention that is not disclosed in Altshuler. Generally speaking, each independent claim recites, in various forms, a device or method in which the *flux of radiation* is used to control the *temperature* in tissue. Specifically, independent method claim 1 recites “*controlling a flux of said radiation to achieve a desired temperature profile in the target region.*” Independent method claim 39 recites “*modulating a flux of said second radiation to control the temperature within at least a first portion of the volume of tissue.*” Independent claim 48 claims a device having “*a second source for generating electromagnetic radiation configured to modulate a flux of radiation from said second source for controlling a temperature profile within at least a first portion of said target region.*”

These limitations are not disclosed in Altshuler. The only explicit reference to the term “flux” in the Altshuler patent refers to “radiance inside the skin at the depth z, caused by a light flux of unit power per length.” (Altshuler Col. 11, lines 20-25.)

Dependent claims 2-3, 5-8, 20-26, 32-33, 35, 37-38, 40-45, 47, 49-51, 54, and 56 are each patentable for at least the same reasons as the independent claims 1, 39 and 48, from which each respectively depends.

Claim Rejections – 35 U.S.C. § 103

Claims 4, 9-15, 18-19, 27-31, 34, 46, 52-53, 55, 57, 59-61 and 68 are rejected under 35 U.S.C. §103 as being anticipated by Altshuler in combination with other references. However,

for the reasons stated above, Altshuler in combination with each of these references does not disclose the recited elements of the currently-amended independent claims 1, 39 and 48. Neither Altshuler nor the additional references cited in combination with Altshuler disclose all of the elements of the claims. Therefore, claims 4, 9-15, 27-29, 34, 46, 52-53, 55, 57 and 59-61 are patentable for at least the same reasons as claims 1, 39 and 48, from which each respectively depends. (Claims 16-19, 30-31, 36, and 62-68 have been cancelled.)


CONCLUSION

In view of the amendments and remarks above, Applicants submit that claims 1-15, 20-29, 32-35, 37-61, and 69-74 are in condition for allowance, and Applicants respectfully request that the Examiner allow those claims. Applicants also request that the Examiner telephone the undersigned, if the Examiner believes that further communication may expedite prosecution of this matter.

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Respectfully submitted,

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